REMARKS

The Claims have been amended by amending Claims 1, 8, 9, 13, 19, and 20; and by canceling Claims 2, 3, and 14.

Claim 1 has been amended in three respects: **(a)** Independent Claim 1 has been amended to refer to a "method for ~~inhibiting or preventing~~ treating" infection. Basis for this amendment is found throughout the specification including, for example, paragraphs 0013 and 0083. **(b)** Independent Claim 1 has also been amended to incorporate a limitation from dependent Claim 2 as originally filed, namely, that the patient is "human." **(c)** Independent Claim 1 has also been amended to incorporate a limitation from Claim 3 as originally filed, namely, that the virus is "human immunodeficiency virus."

Dependent Claims 2 and 3 have been canceled as having become redundant in light of the current amendment to independent Claim 1.

Dependent Claim 8 has been amended to conform to the current amendment to independent Claim 1. No other change in scope is intended in Claim 8.

Claims 9 and 20 have been amended to refer to the Figures that depict the structures of the recited compounds. See M.P.E.P. § 2173.05(s). These amendments are intended as clarifications only, and are not intended to alter the scope of any of the Claims.

Claim 13 has been clarified to refer to a "method for killing ~~or inhibiting~~ the human immunodeficiency virus ~~viruses~~ in or on a nonliving material . . . " The amendment to refer to "human immunodeficiency virus" rather than "viruses" is analogous to the corresponding amendment to Claim 1. The amendment to refer to a "nonliving material" is intended to clarify what was originally intended by the term "material" as used in Claim 13. This clarification is implicitly supported by Claim 13 as originally filed, especially when Claim 13 is contrasted with Claim 1 as originally filed. See also Claim 19 as originally filed, and paragraph 0015 of the specification, fourth sentence.

Dependent Claim 14 has been canceled as having become redundant in light of the current amendment to independent Claim 13.

Dependent Claim 19 has been amended to conform to the current amendment to independent Claim 13. No other change in scope is intended in Claim 19.

Claims 6, 10, 11, 17, 21, and 22 have been held to be withdrawn from examination.

Claims 1, 4-13, and 15-23 remain in the application.

The Restriction and Election of Species Requirements

Both a restriction requirement and an election of species requirement had previously been entered.

The Restriction Requirement. For the reasons given in detail in the Applicants' May 21, 2007 Response, it is respectfully submitted that the restriction requirement should either be withdrawn, or re-characterized as an election of species requirement. Applicants reserve the right to re-present the canceled subject matter at a later date. Applicants also reserve the right to file a petition for review of the final restriction requirement.

However, in the interest of expediting prosecution, at least for the time being the Applicants have amended the Claims to be consonant with Group I as identified in the Restriction Requirement.

The Election of Species Requirement. The July 19, 2007 Office Action held Claims 6, 10, 11, 17, 21, and 22 to be withdrawn as being directed to non-elected inventions. For the reasons given below, it is respectfully submitted that the examined claims are in condition for allowance.

Once the elected claims have been allowed, it then follows that the non-elected Claims should be rejoined and fully examined in the present application as well. In particular, the Office's attention is respectfully directed to M.P.E.P. §§ 821.04 and 821.04(a), which provide for rejoinder of the non-elected Claims in such a case.

Note particularly that rejoinder under M.P.E.P. §§ 821.04 and 821.04(a) does not depend upon whether the original election was made with or without traverse.

The Enablement Rejections

Claims 1, 4, 5, 7-9, 12, 13, 15, 16, 18-20, and 23 were rejected under 35 U.S.C. § 112, first paragraph as lacking enablement. Two grounds were given for the enablement rejection. It is respectfully submitted that both grounds of rejection have been overcome by the present amendments.

Preventing infection. The first ground was that "the specification, while being enabled for the treatment of HIV infection in a patient . . . does not reasonably provide enablement for *preventing*." July 19, 2007 Office Action, par. bridging pp. 2-3. Independent Claim 1 has been amended to now recite a "method for ~~inhibiting or preventing~~ treating a ~~viral~~ human immunodeficiency virus infection . . . ." Likewise, independent Claim 13 has been amended to now recite a "method for killing ~~or inhibiting~~ the human immunodeficiency virus ~~viruses~~ . . . ." It is respectfully submitted that these amendments overcome this ground of rejection.

Other viruses. The second ground was that "the specification, while being enabled for the treatment of HIV infection, does not reasonably provide enablement for treatment of all types of viral infections." July 19, 2007 Office Action, p. 5, first full paragraph. Independent Claim 1 has been amended to now recite a method for treating "a ~~viral~~ human immunodeficiency virus infection . . . ." Likewise, independent Claim 13 has been amended to now recite a method for killing "the human immunodeficiency virus ~~viruses~~ . . . ." It is respectfully submitted that these amendments overcome this ground of rejection.

Enablement summary. It is respectfully submitted that the present amendments overcome the enablement rejections, and that these rejections should accordingly be withdrawn.

The § 112, Second Paragraph Rejections

Two grounds of rejection were entered under 35 U.S.C. § 112, second paragraph.

Compounds identified by reference numerals. Claims 9-12, and 20-23 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite regarding the structures of certain Compounds that are identified by reference numerals. It is respectfully submitted that the clarifying amendments to Claims 9 and 20 overcome this ground of rejection in a straightforward manner that does not require extended discussion. The amendment to refer to certain compounds as depicted in the figures is permissible under M.P.E.P. § 2173.05(s).

Wavelength, intensity, and duration of light exposure. Claims 8 and 19 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite respecting the limitations concerning the wavelength, intensity, and duration of light exposure. It is respectfully submitted that these functional limitations are definite, and comply with § 112, second paragraph. See M.P.E.P. §2173.05(g), which is quoted below in part (all citations omitted):

> **2173.05(g) Functional Limitations**
>
> A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper.
>
> A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step. . . .

> A few examples are set forth below to illustrate situations where the issue of whether a functional limitation complies with 35 U.S.C. 112, second paragraph, was considered.
>
> It was held that the limitation used to define a radical on a chemical compound as "incapable of forming a dye with said oxidizing developing agent" although functional, was perfectly acceptable because it set definite boundaries on the patent protection sought.
>
> In a claim that was directed to a kit of component parts capable of being assembled, the Court held that limitations such as "members adapted to be positioned" and "portions . . . being resiliently dilatable whereby said housing may be slidably positioned" serve to precisely define present structural attributes of interrelated component parts of the claimed assembly.

The limitation in question from Claim 8 (after the present amendment) reads as follows:

> exposing tissue of the patient to light having a wavelength, intensity, and duration sufficient to significantly enhance the compound's treatment of viral infection.

(The corresponding limitation from Claim 19 is similar, though not identical.)

The words in a patent claim should be interpreted as they would be understood by a person of ordinary skill in the art. A person of ordinary skill in the art would readily understand the concepts of exposing tissue to light, finding a suitable wavelength of light to enhance the treatment, finding an intensity of light that will enhance the treatment, and finding a duration of light exposure that will enhance the treatment. Such testing can only be considered routine. None of these expressions would be considered indefinite by a person of ordinary skill in the art. It is respectfully submitted that this ground of rejection should be withdrawn.

Miscellaneous. On a miscellaneous point, in the next communication the Office is requested to clarify which Claims are in fact currently under examination. In the first full paragraph on page 2 of the July 19, 2007 Office Action, the Office stated that Claims 10,

11, 21, and 22 were among those that had been withdrawn from consideration. Yet the second full paragraph on page 7 of the Office Action entered rejections against each of Claims 10, 11, 21, and 22. For the reasons given above under the heading "*The Election of Species Requirement*," it is respectfully submitted that all pending Claims should now be examined. Strictly in the alternative, the Office is respectfully requested to clarify which Claims are currently under examination.

Section 112, second paragraph summary. It is respectfully submitted that all § 112, second paragraph rejections have now been overcome or should otherwise be withdrawn.

The § 103 Rejection

Claims 1, 4, 5, 7-9, 12, 13, 15, 16, 18-20, and 23 were rejected under 35 U.S.C. § 103(a) as being obvious over a proposed combination of Debnath *et al.*, "Anti-HIV-1 activity of carborane derivatives of porphyrins," *Med. Chem. Res.*, vol. 9, pp. 267-273 (1999) and Vicente *et al.*, WO 01/85736.

It is respectfully submitted that there would have been no motivation to make the proposed combination of references. Nor would there have been a reasonable expectation of success, even if one assumed for the sake of argument that some hypothetical motivation might have existed to combine the references (and there would have been no such motivation).

Debnath and Vicente addressed different problems, and employed different classes of chemical compounds. Neither reference suggested that its teachings should be combined with the other.

Debnath teaches that certain ester-linked carborane derivatives of porphyrins possess activity against HIV. In each of Debnath's compounds, the carboranyl groups were linked to the porphyrin macrocycle via ester groups. See Table 1 on page 268, and note particularly the various groups that are shown in Table 1 as the substituents R_1 and R_2.

By contrast, independent Claims 1 and 13 both require "one or more carboranyl groups that are linked to the porphyrin macrocycle by carbon-carbon bonding." Debnath neither teaches nor suggests the use of such compounds. Debnath's ester groups are susceptible to hydrolysis. By contrast, the carbon-carbon bonds linking the boron-containing groups to the porphyrin macrocycle in the claimed inventions are highly resistant to hydrolysis. Nothing in Debnath acknowledged that susceptibility to hydrolysis could be a problem. Nor, for that matter, did anything in Debnath suggest that susceptibility to hydrolysis would not have been desirable. And even if, for some reason, it might have been thought advisable to avoid hydrolysis, nothing in Debnath suggested any modification to resist hydrolysis.

Indeed, most prior carboranyl derivatives of porphyrins have been based on ester or ether linkages. Thus, even if, hypothetically, some motivation might have existed to modify the compounds used in Debnath's technique, a person of ordinary skill in the art would have been far more likely to have chosen other ester- or ether-based compounds known in the field, rather than the carbon-carbon linked compounds of Vicente.

Vicente discloses compounds in which carboranyl groups are linked to a porphyrin macrocycle by carbon-carbon bonding. But Vicente used those compounds for a very different purpose, namely, as neutron capture agents for cancer therapy. Nothing in Vicente suggested using the disclosed compounds as antiviral drugs instead.

When such compounds are used as neutron capture agents for cancer therapy, the advantages of resistance to hydrolysis are straightforward. The mechanism of action is relatively well-understood, and involves a well-characterized nuclear reaction. A boron-10 nucleus captures a low-energy neutron to become boron-11, which subsequently fissions into an alpha particle and a lithium ion:

$$^{10}B(n, alpha)^{7}Li$$

Both the alpha particle and the lithium ion cause damage to tumor cells in close proximity, through ionization processes. See Vicente, p. 1. Thus there is a clear advantage to being

able to deliver large numbers of boron atoms to tumor cells. It would be a distinct disadvantage to non-selectively lose a significant fraction of the boron atoms to the rest of the body through hydrolysis. In the context of neutron capture therapy, knowledge of the mechanism of action allows one to predict with some confidence that resistance to hydrolysis should be an advantage, as such resistance will help retain boron atoms in the vicinity of the tumor, and reduce unwanted side effects in non-target tissues.

By contrast, the antiviral mechanism of action of porphyrin compounds is not understood at the same level of detail as the ^{11}B nuclear fission reaction. On page 267, Debnath describes a proposed mechanism that involves binding of the compounds to the V3 hypervariable loop of the HIV gp120 envelope glycoprotein. However, even if the proposed mechanism is correct, it does not provide the same level of detail, nor the same predictive power as does knowledge of the ^{11}B nuclear fission reaction in neutron capture therapy. While it is straightforward to expect that retention of the carboranyl groups is an advantage for neutron capture-based ionization therapy of tumors, it is much harder to predict whether antiviral activity, or binding to the V3 hypervariable loop of the HIV gp120 envelope glycoprotein, would be helped or hindered by hydrolysis of the ester groups to release free carboranyl groups.

One may read Debnath and Vicente in vain to seek any suggestion for the answer to this question. Perhaps hydrolysis of the carboranyl groups enhances antiviral activity. Perhaps preventing such hydrolysis via carbon-carbon bonds would diminish or even destroy antiviral activity. Until the experimental work had been carried out to answer this question (as reported in the present specification), there would have been no motivation to combine Debnath and Vicente. Still less would there have been any reasonable expectation that such a combination could successfully be used against HIV.

It is respectfully submitted that the claimed inventions would not have been obvious over the cited references, and that the § 103 rejection should be withdrawn.

Miscellaneous

The line corresponding to the Debnath *et al.* (1999) paper was not initialed by the Examiner on the copy of Applicants' November 11, 2003 Information Disclosure Citation that was received by the undersigned with the July 19, 2007 Office Action.

However, the Debnath *et al.* (1999) paper was one of the two references cited by the examiner in the § 103 rejection. Thus it is clear that the examiner has in fact considered the effect of this paper on the claimed inventions. So presumably this entry on the November 11, 2003 IDC was not initialed as the result of a simple clerical error.

Accordingly, and primarily to ensure the accuracy of the list of "References Cited" on the face of any patent to issue from this application, the Examiner is respectfully requested to initial the line corresponding to Debnath *et al.* (1999) on the IDC, and to return a copy of that page to the undersigned with the next communication concerning this application.

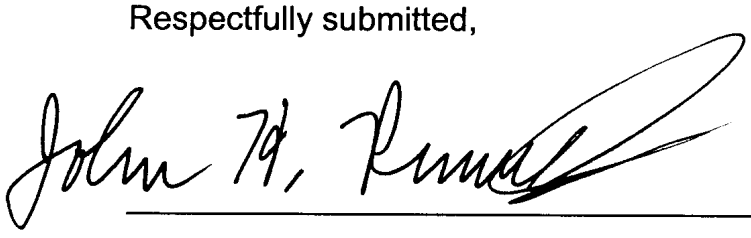
Conclusion

The full scope of all pending Claims should be examined.

The examiner is requested to return an updated copy of the November 11, 2003 IDC to the undersigned with the next communication concerning this application.

Allowance of Claims 1, 4-13, and 15-23 at an early date is respectfully requested.

Respectfully submitted,



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January 10, 2008